



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Baxter Healthcare Recalls Life2000 Ventilator Series Products for Desaturation Events When Connected to an Oxygen Concentrator

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|-------------|--|---|---|
| 3/8/2023 | Life2000 Ventilator System a) REF BT-20-0002, b) REF BT-20-0002A, ventilatory support for the care of individuals | Baxter Healthcare Corporation Deerfield, Illinois | There is the potential for patient desaturation events to occur under certain scenarios when the Life 2000 ventilation system is connected with an oxygen concentrator. |
| 3/8/2023 | Life2000 Ventilator PKG, Hospital a) REF BT20007, b) REF BT-20-0007, ventilatory support for the care of individuals | Baxter Healthcare Corporation Deerfield, Illinois | Potential for patient desaturation events. |
| 3/8/2023 | Life2000 Ventilator PKG a) REF BT200011, b) REF BT-20-0011, ventilatory support for the care of individuals | Baxter Healthcare Corporation Deerfield, Illinois | Potential for patient desaturation events. |
| 3/8/2023 | Life2000 Ventilator REF MS-01-0118, ventilatory support for the care of individuals | Baxter Healthcare Corporation Deerfield, Illinois | Potential for patient desaturation events. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|--------------|--|--------------------------|------------------------|
| I | a) REF BT-20-0002, UDI 00887761978089, Serial Numbers: 120370002037 – 1220500011 | 4279 units Nationwide | January 2023 and Prior |

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|---|---|----------------------|------------------------|
| I | a) REF BT20007, UDI 00887761978089, Serial Numbers: L191001-005 - L2005055-898 | 135 units Nationwide | January 2023 and Prior |
| I | a) REF BT200011, UDI 00887761978089, Serial Numbers: L190606-014, L191011-040, L200127-015, L200204-013; b) REF BT-20-0011, UDI 00887761978089, Serial Numbers: L200226-012, L200226-013, L200226-015 | 8 units Nationwide | January 2023 and Prior |
| I | UDI 00887761978089, Serial Numbers: L1912010-050 - L1912025-007 | 71 units Nationwide | January 2023 and Prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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